REMARKS

In the Final Action dated November 21, 2005, the Examiner has modified the restriction requirement and has rejoined claims 15, 37, and 38 with claims 16-18 in the examination. Claims 19-29 and 39-40 are withdrawn from consideration as directed to non-elected subject matter. Claims 16-18 are rejected. Claims 15 and 37-38 are objected to.

This Response addresses each of the Examiner's rejections and objections. Applicants therefore respectfully submit that the present application is in condition for allowance, or at least in better condition for appeal. Favorable consideration of all pending claims is therefore respectfully requested.

In the first instance, Applicants have canceled claims 19-29 and 39-40, directed to non-elected subject matter. Applicants reserve the right to pursue these claims in a divisional application.

Applicants have also amended a typographical error in claim 16 by replacing the term "X_2" with "X_3". Support for this amendment is found, e.g., in the specification and in original claim 8. Those skilled in the art would recognize the reference to "X_2" is a typographical error. No new matter is introduced by this amendment.

Claims 15, 37 and 38 are objected to as depending from canceled claim 8.

In response, Applicants respectfully submit that claims 15 and 38 have been canceled, rendering the objection to these claims moot. Claim 37 has been rewritten as an independent claim and has incorporated certain characterizations in original claim 8. No new matter is introduced by this amendment. Further, claims 40-41 are added, which depend upon claim 37. Claims 40-41 are supported by original claims 9-10. No new matter is introduced. In view of the

instant amendment, the objection to claims 15 and 37-38 is obviated and withdrawal thereof is respectfully requested.

Claims 16-18 are rejected under 35 U.S.C. §112, second paragraph, as allegedly indefinite and incomplete. The Examiner maintains that claim 16 recites a circular method without actual method steps. Additionally, the Examiner maintains that the term "reactivity" is not defined in the specification.

It appears to Applicants that the Examiner may have been confused by the term "reactivity", which is recited twice in claim 16: once in the preamble and once in step (2) of the claimed method. Applicants have amended claim 16 to clarify that the first recitation of "reactivity" refers to the reactivity within a subject to IDDM autoantigens, whereas the second recitation of "reactivity" refers to the reactivity of the isolated cells *in vitro* towards the identified peptide. Therefore, the claimed method does include actual method steps, which are performed *in vitro*.

Further, Applicants respectfully submit that the word "reactivity" is commonly used in the field and is also well understood by those skilled in the art to mean the response of cells upon direct or indirect interaction with a molecule or entity. The response may manifest as changes in the function, activity, composition or behavior of the cells. In the context of the present claims, those skilled in the art would understand that the first recitation of "reactivity" means the response of cells in the subject upon an interaction with IDDM autoantigen(s); and the second recitation of "reactivity" means the response of cells upon contact *in vitro* with the specified peptide. Further, the specification clearly discloses how the reactivity of cells towards a peptide can be determined by various assays *in vitro*. See, e.g., page 9, lines 15-19. Therefore,

Applicants respectfully submit that the meaning of the term "reactivity" is clear to those skilled in the art, especially in light of the specification.

In view of the instant amendment and the foregoing remarks, Applicants respectfully submit that the rejection of claims 16-18 under 35 U.S.C. §112, second paragraph, is overcome. Withdrawal of the rejection is respectfully requested.

Claims 16-18 are rejected under 35 U.S.C. §112, first paragraph, for allegedly failing to satisfy the written description requirement. The Examiner indicates that the specification discloses measuring reactivity only by specific assays. The Examiner contends that the broader method of generically measuring the reactivity of a subject to IDDM autoantigen is not adequately described in the specification.

Applicants respectfully submit that that the present inventors have uniquely identified immunodominant epitopes in GAD and proinsulin molecules, which are autoantigens implicated in IDDM. Given this identification provided by the present invention, the reactivity to IDDM autoantigens in a subject can be determined by measuring, *in vitro*, the reactivity of peripheral blood cells or T-cells obtained from such subject towards a peptide containing an identified immunodominant epitope. Applicants respectfully submit that the methods and assays for determining the reactivity of cells, such as cells obtained from peripheral blood of a patient, towards any peptide antigen, are well known to those skilled in the art. These assays *per se* are not the key feature of the present invention.

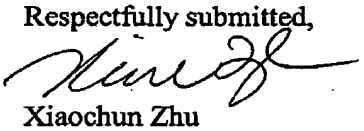
An applicant is not required to describe what is already known to those skilled in the art. The law is clear in that what is conventional or well known to one skilled in the art need not be disclosed in detail. See Hybritech Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1986); Vas-Cath Inc. v. Mahurkar, 935 F.2d 1555, 1563, 19

USPQ2d 1111, 1116 (Fed. Cir. 1991); Martin v. Johnson, 454 F.2d 746, 751, 172 USPQ 391, 395 (CCPA 1972).

Therefore, Applicants respectfully submit that the claimed subject matter is adequately described in the specification in a manner that satisfies the written description requirement. Withdrawal of the rejection of claims 16-18 under 35 U.S.C. §112, first paragraph, is respectfully requested.

In view of the foregoing amendments and remarks, it is firmly believed that the subject application is in condition for allowance, which action is earnestly solicited.

Respectfully submitted,



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